# PolyHeme® Trauma Trial

Community Consultation

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## Clinical Investigator


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## Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying blood substitute called PolyHeme®
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website ***www.northfieldlabs.com***

## Study Purpose

***To evaluate the life-saving potential of PolyHeme® when given to severely injured and bleeding patients in "hemorrhagic shock," starting at the scene of injury***

## What is Hemorrhagic Shock?

***Hemorrhagic***: massive loss of blood

***Shock***: life-threatening condition

- Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- Might lead to death

## Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock

## What is the Standard of Care?

***Represents the current treatment***

| *In the Ambulance* | *In the Hospital* |
|---|---|
| The patient receives salt water (blood is not available) | The patient receives salt water and donated blood |

## Standard of Care Limitations

***In the Ambulance***

- Salt water does not carry oxygen, unlike blood
- Without enough oxygen, the body and its internal organs have difficulty functioning and can stop working (organ failure)

## Standard of Care Limitations

***In the Hospital***

- Donated blood takes time (45-60 minutes) to be matched for each patient
- Patients who receive more than 6 units of donated blood in the first 12 hours have an increased risk of organ failure

## What is PolyHeme®?

***A blood substitute that carries oxygen***

1 unit of PolyHeme
=
1 unit of blood

## What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- Immediately available
- Reduced risk of viral disease (viral load reduced over a billion times)

## Why Use PolyHeme®?

- PolyHeme was developed to treat blood loss when blood is not available
  - Blood is not available in the ambulance
  - PolyHeme will be immediately available in the ambulance and carries oxygen
- PolyHeme can reduce the use of donated blood in the first 12 hours after injury, and might avoid potential organ failure

## Why Use PolyHeme®?

***To improve survival of severely injured and bleeding patients***

## PolyHeme® Experience

- PolyHeme has been studied in more than 300 individuals and 5 different clinical trials
- PolyHeme has been extensively studied in hospitalized trauma patients
- ***PolyHeme has kept trauma patients alive when they have lost all of their own blood***

## PolyHeme® Experience

Past studies have shown that PolyHeme

- Carries as much oxygen as blood (1 unit of PolyHeme = 1 unit of blood)
- Reduces need for donated blood
- Has not caused organ damage
- Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units)

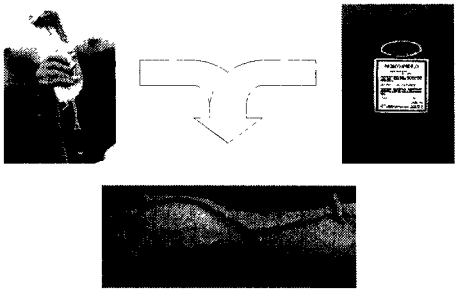
## Trial Design: Before the Hospital

***Severely injured trauma patients will be assigned to either one of two groups by chance***


***Control***
Receive salt water

***Test***
Receive PolyHeme®

## Ambulance Infusion



## Trial Design: At the Hospital

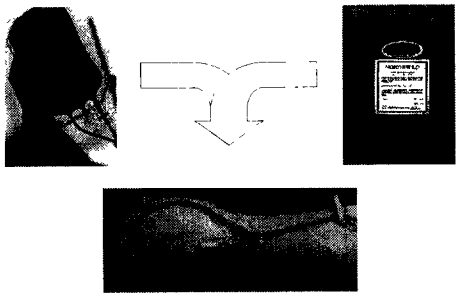
***Control***

- Salt water for hydration
- Donated blood to boost oxygen levels

***Test***

- Salt water for hydration
- PolyHeme® to boost oxygen levels
- Maximum dose of 6 units during first 12 hours
- Donated blood will be used thereafter

## Hospital Infusion



## Who Would Be Included?

***Patients at risk of dying***

- Who have sustained severe injuries
- Who have lost a large amount of blood and are in shock
- Who are at least 18 years old
- Who are of either gender (male or female)

## Who Would Be Excluded?

- Patients who are obviously pregnant
- Patients who have severe head or brain injuries
- Patients who have "unsurvivable" injuries
- Patients who require CPR
- Patients with known objections to blood transfusions
- Patients with known orders not to resuscitate

## FDA Review

- Northfield Laboratories received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of an exception from informed consent requirements for this study

## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs investigational)
- Doctors describe each of these potential treatments

## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

## What is Exception from Informed Consent?

***Patients are enrolled in a research study without giving their informed consent***

## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- ***Patients' lives must be at risk***
- Available treatments are not satisfactory
- Patients are unable to give consent
- Potential risks are reasonable

## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Participation in the research could provide a direct benefit ***(increased survival)*** to the patient
- The research could not be practicably carried out without an exemption

## Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study
- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study

## Consent Safeguards

***The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time***

## Potential Benefits of PolyHeme®

- ***Might increase the likelihood of survival***
- Can enhance the amount of vital oxygen in the patient's blood
- Is compatible with all blood types
- Is immediately available
- Has reduced risk of viral disease (viral load reduced over a billion times)

## Potential Risks of PolyHeme®

- Rash
- Increased blood pressure
- Kidney or liver damage
- Viral infection (HIV, hepatitis, etc.)
- Unforeseen happenings

## Patient Protection

The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- Assures patient safety
- Monitors community feedback

## Patient Protection

- The IRB will decide whether or not to allow this hospital to participate in the PolyHeme® trial
- An independent data monitoring committee will oversee the trial
- The FDA will be kept informed of the trial's progress

## If We Participate...

- The results of the study will be revealed to the community after the trial has been completed
- Those who do not want to participate in the study can exclude themselves

Questions
or
Comments?